IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
CHEN et al.

Application No.: 10/563,078 Group Art Unit: 4173

Filing Date: June 8, 2006 Examiner: Nissa M. Westerberg

For: Matrix Adjuvants And The Drop Pills Prepared With Them

DECLARATION UNDER 37 C.F.R. § 1.132

I Chen Jianming, do hereby declare as follows:

1. My name is Chen Jianming. I received a bachelor's degree in pharmacology from the Second Military Medical University in 1987, an M.S. in pharmacology from ShenYang Pharmaceutical University in 1994 and a Ph.D from ShenYang Pharmaceutical University in 1999. I completed my post doctoral research at the Second Military Medical University in 2001.

2. I began my career at the Second Military Medical University, where I focused on the research and development of new drug formulation and new pharmaceutical technology. I authored numerous articles in scientific journals published in P. R. China and other countries.

3. I am the inventor of the subject matter of the above-identified patent application, application serial no. 10/563,078 (the '078 application).

4. It is my understanding that the Examiner has maintained the rejection of claims of the '078 application under 35 U.S.C. §102(b) as allegedly anticipated by Okada et al. (US 6,455,053) and by DuRoss (US 5,075,291); and under 35 U.S.C. §103(a) as allegedly obvious over Okada et al. and DuRoss.

5. I have read at least the pertinent portions of the Okada et al. and the DuRoss references as it applies to the 102(b) rejections of claims 1, 3, 5, 13 and 14 and the 103(a) rejection of claims 1-3, 6, 7, 13 and 14.

6. Comparative tests were conducted comparing the drop pill of the '078 application with the product of Okada et al. so as to determine hardness and disintegration of the respective products. Identical formulations with the formulations of Example 12 of Okada et al were used in the product identified as "the drop pill of the '078 application" and "product disclosed by Okada et al." The difference is the process used to prepare each product. That is, the product identified as "the drop pill of the '078 application" with the identical formulations of Example 12 of Okada et al was prepared according to the method of Example 1 of the '078 application which provides that pellets of a molten mixture of the pharmaceutical active ingredient and the matrix adjuvant be dropped into a liquid coolant and the product identified as the "product disclosed by Okada et al. " was prepared according to the method of Example 12 of the Okada et al. which provides that a suspension of the pharmaceutical active ingredient and saccharide be charged into a mold and air-dried, following by additional slow drying.

7. Data with comparative results of "the drop pill of the '078 application" and "product disclosed by Okada et al." was submitted to the United States Patent and Trademark Office in my Declaration dated January 11, 2010. The data submitted shows the differences in structure and properties between the drop pill prepared in accordance with the method of Example 1 of the '078 application and the product prepared in accordance with the method of Example 12 of Okada et al. in the case that the drop pill of the '078 application and the product of Okada et al have completely identical formulations.

8. The data shows that as compared to the product prepared in accordance with Example 12 of Okada et al., the drop pill prepared in accordance with Example 1 of the '078 application has an average hardness that is higher and a significantly longer average disintegration time. Further, the drop pill produced in accordance with the '078

application produces a product that has higher density and a smoother surface.

9. Comparative tests were also conducted comparing the drop pill claimed in the '078 application with the product of DuRoss to determine the crystalline state and the dissolution rate. Identical formulations using cimetidine as the active ingredient, sorbitol as the adjuvant and identical components were used in the product identified as "the drop pill of the '078 application" and "product of DuRoss" The difference is the process used to prepare each product. That is, the product identified as "the drop pill of the '078 application was prepared according to the method of Example 1 of the '078 application and the product identified as the "product of DuRoss" was prepared according to the method of Example 5 of DuRoss. Example 1 of the '078 application provides that pellets of a molten mixture of the pharmaceutical active ingredient and the matrix adjuvant be dropped into a liquid coolant. Example 5 of DuRoss discloses placing a melt, consisting of the pharmaceutical active ingredient and a sugar alcohol, on a tray to dry and slowly cooling until crystallized. The crystallized product is then ground to provide a powder that can be make into tablets.

10. Data with comparative results of "the drop pill of the '078 application" and "product of DuRoss" was submitted to the United States Patent and Trademark Office in my Declaration dated January 11, 2010. The data shows that the drop pill claimed in the '078 application has a different crystalline state, different dissolution rates from those of the product of DuRoss in the case that the drop pill of the '078 application and the product of DuRoss have completely identical formulations.

11. The data shows that as compared to the product prepared to the product of DuRoss, the drop pill prepared in accordance with Example 1 of the '078 application has different pharmaceutical properties from the product of DuRoss.

12. It is my opinion, based on the comparative tests submitted to the United States Patent and Trademark Office in my Declaration dated January 11, 2010, that the drop

pill of the '078 application is remarkably different from the product disclosed by Okada et al. and the product of DuRoss both in structure and properties in the case that the drop pill of the '078 application and the product of DuRoss have completely identical formulations. I expect that these differences result in a drop pill that is more resistant to pressure and is easier to transport and store.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under '1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent.

Date: June 7, 2010

Chen Jianming

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